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10/536,617	03/13/2006	Danette Vanessa Choi	A36515-PCT-USA-070013.020	9136
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CHAWLA, JYOTI				
ART UNIT		PAPER NUMBER		
1794				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DLNYDOCKET@BAKERBOTTS.COM

Office Action Summary

Application No.

10/536,617

Applicant(s)

CHOI, DANETTE VANESSA

Examiner

JYOTI CHAWLA

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date 5/26/05 and 9/28/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claims 1-20 are examined in the application.

Information Disclosure Statement

The information disclosure statement filed 5/26/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Copy of original document JP 08-056562 A has not been received and only English language abstract is among the received documents. It has been placed in the application file, but the information referred to therein has not been considered. For the purpose of expediting the prosecution, a copy of original document JP 08-056562 A and machine translation is attached herewith for future reference.

Claim Objections

Claim 13 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 12. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(A) Claims 1-3 and 5-7, 15-16 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (US 4089985).

Regarding claims 1-3 and 15, Wolff teaches of a method for preparing a papaya preparation comprising cooking the Carica papaya fruits in an aqueous medium (Column 2, lines 43-68) wherein the volume of the aqueous medium is at least twice of the water content of the fruits (Column 2, lines (65-68), as claimed. Regarding cooking the papaya Wolff teaches that water added to papaya is at 71°C and during the process the temperature is raised to 91 °C-99 °C (Column 3, lines 3 to 5 and 20-25 , Column 4, lines 40-50), which will result in cooking the papaya. Regarding the limitation of cooling the cooked papaya fruits for a period of at least 30 minutes in an oxygen-containing atmosphere Wolff teaches of cooling as recited (Column 3, lines 66-68). Regarding the optional limitation of homogenizing the papaya fruits it is not a positive limitation and is therefore not required in the method of processing papaya as claimed. Regarding

papaya product being a puree, Wolff teaches of papaya product wherein water is added to papaya meat in the recited range of the applicant, therefore, Wolff teaches of a papaya puree product as recited in claims 1, and 15.

Regarding the time for cooking and cooling for at least 30 minutes at normal pressure (claim 1) and at least 2 hours (claim 2), Wolff teaches of heating and blending together and also teaches that the time in blender required to raise the temperature and homogenize papaya depends on the type of blender and speed of blending (Column 3, lines 1-20 and Column 4. Wolff also teaches of a minimum of 18 minutes to blend papaya (Column 2, line 13-15). Wolff further teaches of pasteurization and further teaches that minimum time required for pasteurizing at 65°C is 30 minutes. Thus, processing or cooking and cooling times vary from one food to another and desired temperature of the finished food. It is noted that it was well within the purview of one of ordinary skill in the art at the time of the invention to vary food cooking and processing time based on cooking temperature employed, equipment available, amount of food cooked and desired consistency of finished product. Therefore, to heat a food product for a specific time (at least for 30 minutes as recited), would have been a matter of routine determination for one of ordinary skill in the art at the time of the invention. One of ordinary skill would have been motivated to adjust the cooking time at least for the purpose of ensuring that the papaya product is cooked to a desired level.

Similarly regarding the time of cooling, Wolff teaches of cooling but is silent about the time of cooling as recited in claims 1 and 3. Cooling times vary at least based on the temperature of the cooled product desired, The cooling conditions, such as stirring or agitation etc., which are routinely determinable by one of ordinary skill in the art. Therefore, to cool a food product for a specific time (at least for 30 minutes as recited), would have been a matter of routine determination for one of ordinary skill in the art at the time of the invention. One of ordinary skill would have been motivated to adjust the cooling time at least based on the initial temperature of cooked papaya product, the type of equipment or container and the method of cooling employed (e.g., stirring or

putting in a wide mouth pot will cool a hot product faster than no stirring or a long and narrow pot) and based on the desired final temperature of the cooled product.

Regarding claim 5, Wolff teaches that papaya fruits are peeled and stoned prior to cooking (Column 2, lines 54-60).

Regarding claim 6, Wolff teaches that obtained papaya product is pasteurized (Column 5, lines 1-20).

Regarding claim 7, Wolff teaches of papaya product which is ripe (Column 2, lines 50-65).

Regarding claim 18, Wolff teaches of papaya product where the fruit is blended (Column 3, line 18), which crushes the fruit product as recited.

Regarding the water content of the puree as recited in claims 16 and 19, Wolff teaches that water can be added up to 3 parts of water for one part of papaya meat (Column 2, lines 64-68), before blending and heating. Thus, the amount of water in the papaya product as taught by Wolff can be varied. It is noted that fruit based purees can be made thick or thin by varying the amount of liquids at least based on the intended use. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Wolff for the purpose of making the papaya product more or less viscous as desired, by modifying routinely determinable parameters, such as, the amount of water or liquids added, time and temperature of cooking etc. One of ordinary skill would have been motivated to modify Wolff and have the water content of the product in the range of 70-80% (claim 19) at least for the purpose of making the papaya product viscous enough for the intended use as a puree. One would have been further motivated to do so to maintain desirable nutritional and organoleptic characteristics of the papaya product.

Regarding claims 1-3, 16 and 19, further, attention is invited to *In re Levin*, 84 USPQ 232 and the cases cited therein, which are considered in point in fact situation of the instant case. At page 234, the Court stated as follows:

This court has taken the position that new recipes or formulas for cooking food which involve the addition or elimination of common ingredients, or for treating them in ways which differ from the former practice, do not amount to invention, merely because it is not disclosed that, in the constantly developing art of preparing food, no one else ever did the particular thing upon which the applicant asserts his right to a patent. In all such cases, there is nothing patentable unless the applicant by a proper showing further establishes a coaction or cooperative relationship between the selected ingredients, which produces a new, unexpected and useful function. In *re Benjamin D. White*, 17 C.C.P.A. (Patents) 956, 39 F.2d 974, 5 USPQ 267; In *re Mason et al.*, 33 C.C.P.A. (Patents) 1144, 156 F.2d 189, 70 USPQ 221.

(B) Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (US 4089985) in view of Swensen (US 5840356).

Wolff has been applied to reject claims 1-3, 5-7, 15-16 and 18-19 under 35 U.S.C. 103(a) above.

Regarding claim 4, Wolff teaches of processing papaya wherein acids, including citric acid is added to papaya (Column 3, lines 5-15), but does not teach the pH of the product. Swensen teaches processing of fruit purees, wherein the fruits include papaya (Swensen, Column 2, lines 18-21). Swensen teaches that acidic pH helps to preserve the fruit purees. Swensen teaches of addition of edible acids, including citric acid in sufficient quantity to maintain a desired pH range of 2.3 to 3.8 (Column 3, lines 10-20), which includes values in applicant's recited range of 3.5 to 5.0. Thus, addition of citric acid to acidify fruit products was known at the time of the invention (Wolff and Swensen). Further, fruit purees having pH in applicant's recited range were known at

the time of the invention (Swensen). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Wolff and add citric acid in a sufficient amount, such that the pH of the papaya fruit product falls in the desired pH range as taught by Swensen. One of ordinary skill would have been motivated to modify Wolff at least for the purpose of acidifying papaya puree to a pH level where the acid acts as a preservative and also enhances the effect of other preservatives, such as, sodium benzoate and potassium sorbate if present in the fruit composition.

Regarding the addition of citric acid to cooled papaya puree, Wolff also teaches of adding citric acid before blending the papaya product (as Wolff teaches of heating (cooking) and blending steps together) and the applicant teaches adding citric acid to the papaya product after it has been cooled (before blending). It is noted that addition of citric acid is done in such a manner that citric acid can be homogeneously mixed in the papaya product. It would have been a matter of routine determination and thus, obvious to one of ordinary skill in the art at the time of the invention to add citric acid to papaya product, at a stage in processing wherein the acid can be dispersed homogeneously in the food product. One of ordinary skill would have been motivated to do so in order to obtain a uniform taste and flavor in the papaya product.

(C) Claim 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (US 4089985) in view of the combination of IDS document by Emma Dawson (The medicinal properties of Papaya), hereinafter Dawson, Chandalia et al (Beneficial Effects of High Dietary Fiber Intake in Patients with Type 2 Diabetes) and Katsuki Imao et al. (Free radical scavenging activity of fermented papaya preparation and its effect on lipid peroxide level and superoxide dismutase activity in iron-induced epileptic foci of rats).

Wolff has been applied to reject claims 1-3, 5-7, and 15-16, 18-19 under 35 U.S.C. 103(a) above.

Wolff teaches papaya product as recited in claim 1, but is silent about the method of using papaya product to treat certain disorders. Regarding claims 8-11, Dawson discloses the medicinal properties of papaya, namely the use in dyspepsia and other digestive disorders (claims 8 and 9), rheumatism, an immune system disorder (Claim 10) chronic wounds, burns and ulcers (claim 11), enlarged tonsils as well as the conventional application in the countries of origin in the form of jelly, jam or fruit juice (Dawson, pages 1 and 2). It is also indicated that the enzyme papain present in papaya is not destroyed by heating.

Regarding the method of using papaya product to reduce insulin requirement, as recited in claims 12 and 13, Chandalia et al teach that inclusion of high insoluble fiber in foods including papaya improves glycemic control (Diet section, paragraph 3, after Table 1). The article emphasizes that improved glycemic control and decreases degree of hyperinsulinemia in patients with Type -2 diabetes.

Further, Katsuki Imao teaches of an association between antioxidants present in papaya and their positive effect in treatment of aging related diseases, such as Parkinson's disease (Page 11 , paragraphs 1-3).

Thus, papaya inherently has properties to treat certain disorders as recited in claims 8-14. Therefore, It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Wolff and specify the benefits of dietary intake of papaya product. One of ordinary skill would have been motivated to modify Wolff at least for the purpose of educating the consumer of the multitude of benefits of consuming prophylactically or therapeutically effective amounts of papaya product.

(D) Claims 17 and 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (US 4089985) in view of Nakayama (JP 08056562 A) (English Abstract and machine translation).

Wolff has been applied to reject claims 1-3, 5-7, and 15-16, 16-19 under 35 U.S.C. 103(a) above.

Regarding the sugar content of the puree as recited in claims 17 and 20, Wolff teaches of 4 tablespoons of sugar to 12 ounces of papaya, but the amounts taught by Wolff are approximate (Column 3, lines 3-15). Thus, the amount of sugar in the papaya product as taught by Wolff can be varied. Nakayama teaches of a cooked papaya product containing 25-35% sugar, which falls within applicant's recited range for claims 17 and 20. Further, it is noted that fruits vary in their sweetness from one plant to another, one season to another and the amount of sugar added to the puree can be varied in order to achieve a consistent fruit puree product from one batch to another. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Wolff and change the amount of sugar added to the puree based on the teaching of Nakayama, at least for the purpose of making a sweet papaya based product of Wolff, with sweetness and other organoleptic properties in the desired range in the finished product. One of ordinary skill would have been motivated to modify Wolff and have the sugar content of the product in the recited range at least for the purpose of making a papaya product with consistent and desirable nutritional and organoleptic characteristics.

Further, attention is invited to *In re Levin*, 84 USPQ 232 and the cases cited therein, which are considered in point in fact situation of the instant case. At page 234, the Court stated as follows:

This court has taken the position that new recipes or formulas for cooking food which involve the addition or elimination of common ingredients, or for treating them in ways which differ from the former practice, do not amount to invention, merely because it is not disclosed that, in the constantly developing art of preparing food, no one else ever did the particular thing upon which the applicant asserts his right to a patent. In all such cases, there is nothing patentable unless the applicant by a proper showing further establishes a coaction or cooperative relationship between the selected ingredients, which produces a new, unexpected and useful function. In *re Benjamin D. White*, 17

C.C.P.A. (Patents) 956, 39 F.2d 974, 5 USPQ 267; In re Mason et al., 33 C.C.P.A. (Patents) 1144, 156 F.2d 189, 70 USPQ 221.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTI CHAWLA whose telephone number is (571)272-8212. The examiner can normally be reached on 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on (571) 272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JC/
Examiner
Art Unit 1794

/JENNIFER MCNEIL/

Supervisory Patent Examiner, Art Unit 1794